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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/768,991	01/23/2001	Gary K. Michelson	101.0101-00000	4198
22882	7590	10/03/2003		
MARTIN & FERRARO, LLP 1557 LAKE O'PINES STREET, NE HARTVILLE, OH 44632			EXAMINER PHILOGENE, PEDRO	
			ART UNIT 3732	PAPER NUMBER 14
DATE MAILED: 10/03/2003				

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/768,991

Applicant(s)

MICHELSON, GARY K.

Examiner

Pedro Philogene

Art Unit

3732

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 04 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-16, 17-54, 56-150 and 152-198 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-54, 56-150 and 152-198 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 15. 6) ☐ Other: \_\_\_\_\_

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/4/03 has been entered.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-16, 18-25, 119-123, 149, 153-159, 195 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, line 16, the term "said plurality of bone screw receiving holes" lack prior antecedent basis.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-14, 18-34,37-52, 56-71,74-91,94-109,112-150, 152-198 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fraser (6,432,106) in view of Henderson et al. (6,066,175) in view of Benzel et al (6,214,005).

With respect to claims 1,26,44,62,81,100, Fraser discloses a spinal implant (10) for insertion at least in part across at least the height of a disc space between adjacent vertebral bodies (52,54), the implant comprising opposed upper and lower surfaces (16,18) adapted to be placed toward and in contact each of the adjacent vertebral bodies, respectively from within the disc space; as best seen in figs. 7-9; a leading end (14) for insertion into the disc space and between the adjacent vertebral bodies; a trailing end (12) opposite the leading end, the trailing end having an exterior surface and an outer perimeter with an upper edge and a lower edge adapted to be oriented toward the adjacent vertebral bodies, respectively, as best seen in Figs. 1-9, the trailing end having a maximum height, as measured from the upper edge to the lower edge along the longitudinal axis of the human spine, the maximum height being adapted to fit within the disc space and between the vertebral bodies adjacent to the disc space; as best seen in Fig: 9; a bone screw (46,48) having a leading end for placement in the vertebral body and a trailing end opposite the leading end adapted to cooperatively engage the implant so as to prevent further advancement of the bone screw into the bone and to be retained within one of the plurality of bone screw receiving holes.

It is noted that Fraser did not teach of a plurality of bone screws receiving holes in the trailing end of the implant, as claimed by applicant. However, in a similar art, Henderson et al evidences the use of a spacer having a plurality of bone screws

receiving holes in the trailing end of the implant to receive screws that have trailing end extending beyond the maximum height of the trailing of the implant immediately adjacent thereto to fasten the spacer to the adjacent bones.

Therefore, given the teaching of Henderson et al., it would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate the screws holes of Henderson et al., in the fusion cage of Fraser to fasten the fusion cage to the vertebrae.

It is noted that the above combination of references did not teach of at least one of the hole adapted to only partially circumferentially surround a trailing end of a bone screw adapted to be received therein, at least one of the bone screw receiving holes passing through the exterior surface and one of the edges so as to permit the trailing end of the bone screw to protrude beyond the one of the edges; as claimed by applicant. However, in a similar art, Benzel et al evidence the use of a plurality of bone screw holes adapted to only partially circumferentially surround a trailing end of a bone screw adapted to be received therein and passing through an edge to permit the trailing of the bone screw to protrude beyond the end of the edge to block movement of the implant, and thereby its associated bone portions.

Therefore, given the teaching of Benzel et al. it would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate the partially circumferentially screw holes in the device Fraser/Henderson et al., to block movement of the implant, and thereby its associated vertebral portions.

As to claim 44, the trailing end being adapted to receive at least a portion of a bone screw passing therein that extends beyond the maximum height immediately adjacent thereto, is shown in FIGS. 1-16 of Henderson et al..

As to the perimeter having a gap, wherein at least one of the bone screw receiving holes interrupting only the upper edge of the trailing end, and another one of the bone screw receiving holes interrupting only the lower edge of the trailing end, it is shown by Benzel et al. in Figs.7-10.

With respect to claims 2-14,18-34,37-43,45-52,56-61,63-71,74-80,82-91,94-99,101-109,112-148,195-198, the above combination of references discloses all the limitations as set forth in column 3-13, lines 1-67 of Benzel et al., and in column 2-4, lines 1-67 of Fraser.

With respect to claims 149, 150, 152, Henderson et al., disclose a device wherein at least one of the bone screw receiving holes passes through the upper edge, and at least one of the bone screw receiving holes passes through the lower edge of the trailing end; and as best seen in Figs. 15,16.

With respect to claims 153-194, Fraser discloses, column 3, lines 1-12, column 4, lines 5-10, in combination with the fusion cage, the use of insertion device, distraction and insertion device, the removal of the disk, the preparation of the implant area. Therefore, given the teaching of Fraser, the use of any given instrument in the preparation and implantation of a fusion cage is old and well known in the art; thus, using one or the other would be an obvious mechanical choice.

Claims 15,16,35,36,53,54,72,73,92,93,110,111 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fraser (6,432,106) in view of Henderson et al. (6,066,175) in view of Benzel et al (6,214,005) Further in view of Lowery et al (5,364,399).

With respect to the above claims, it is noted that the above combination of references did not teach of a lock for retaining at least one or a plurality of bone screws within an implant, as claimed by applicant. However, in a similar art, Lowery et al evidence the use of a lock to engage the heads of the screws and provide a rigid fixation of the screws to the implant.

Therefore, given the teaching of Lowery et al., it would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate a lock in the device of Fraser/Henderson et al./Benzel to engage the heads of the screws and provide a rigid fixation of the screws to the implant.

### ***Response to Amendment***

Applicant's arguments with respect to claims 1-16,17-54,56-150,152-198 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Wo 98/48738      11-1998      Ctozet.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pedro Philogene whose telephone number is (703)


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308-2252. The examiner can normally be reached on Monday to Friday 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin P Shaver can be reached on (703) 308-2582. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Pedro Philogene  
September 26, 2003

  
PEDRO PHILOGENE  
PRIMARY EXAMINER